

REMARKS

Obvious-type double patenting

Claims 1-4 and 7 are rejected for obviousness-type double patenting as being unpatentable over claims 1-12 of United States Patent No. 7,514,437 ("Borthwick"). The Examiner reasoned that although the conflicting claims are not identical, they are not patentably distinct from each other because presently claimed invention is generically claimed in the issued patent. Applicant requests reconsideration and withdrawal of the rejection for the reasons set forth herein.

It is well-established that a person may obtain a valid patent on an improvement even though it is dominated by the basic or general patent of another.¹ In *In re Kaplan*, 789 F. 2d 1574, 229 USPQ 678 (Fed. Cir. 1986), the Federal Circuit reversed the board's double patenting rejection and held that a double patenting rejection cannot be justified solely on the ground that the subject matter of a claim in a second patent or patent application is "dominated" by the claims in a first patent. In other words, double patenting does not arise automatically when the broader claim embraces the subject matter defined by the narrower claim.

The key question in considering a double patenting issue is does any claim in the application define merely an obvious variation of an invention claimed in the patent. Here, applicant claims a selection invention, which is traditionally allowable if other requirements of an invention are also satisfied. Claim 1 encompasses a narrow genus of two compounds and their salts thereof. By comparison, even the narrowest teaching of Borthwick (claims 3-6) encompasses thousands of compounds, most of which are not claimed by the instant application. The fact that the Borthwick claims encompass the

¹ 3A-9 Chisum on Patents § 9.03

current claims does not render per se double patenting. Furthermore, because the current claims are so narrow compared with Borthwick, they cannot be considered obvious variants of any Borthwick claim. Applicant contends that outstanding Office Action fails to make out a proper obviousness-type double patenting rejection. Applicant therefore respectfully requests the double patenting rejection be withdrawn.

Additionally, the Examiner states that the instant compounds would have been obvious because one skilled in the art would have been motivated to prepare all the compounds embraced by the genus of Borthwick with the expectation of obtaining additional beneficial compounds. Applicant notes that *prima facie* obviousness is not an element of obvious-type double patenting. Further, Applicant respectfully disagrees with the examiner's analysis of *prima facie* obviousness.

The Federal Circuit has noted that a prior art disclosure of a genus does not make *prima facie* obvious every member that falls within the genus. See *In re Baird*, 16 F 3d 380, 383 (Fed. Cir. 1994). The prior art disclosure of a genus which includes a subsequently claimed species must still provide the suggestion and motivation to make the particular species claimed as the invention in order for the motivation element of *prima facie* obviousness to be established. In this case, the cited art fails to suggest making the necessary modifications to achieve the current compounds and fails to suggest that the current compounds would have improved properties.

The Examiner relied on Merck & Co. b. Biocraft Laboratories, 874 F. 2d 804 (Fed. Cir. 1989) for the proposition that a prior disclosure of a genus of useful compounds is sufficient to render *prima facie* obvious a species falling within the genus. However, as pointed out by a later decision in Pfizer Inc. v. Synthon Holdings BV, 2006 U.S. Dist. LEXIS 63063 (M.D.N.C. Aug. 31, 2006), this argument is an overstatement of what the Federal Circuit actually determined in Merck. In Merck, the prior art patent taught a

genus that included about 1,200 species combinations of diuretics, one of which was the patentee's claimed combination. Merck at 806-07. Thus, in Merck, the Federal Circuit found the patentee's combination to be *prima facie* obvious, even though neither of the diuretics were identified as *preferred* in the patent, because the prior art specifically taught that each combination, including the patentee's combination, would work. See Merck at 807-08. Therefore, Merck should apply only to situations where the prior art has specifically taught the claimed invention. Unlike Merck, the instant compounds are not specifically taught by Borthwick.

The examiner also misquoted In Re Susi 440 F. 2d 442, 445, regarding *prima facie* obviousness. Applicant requests that the Examiner state where in In re Susi is the position that a prior art which disclosed genus of useful compounds is sufficient to render *prima facie* obvious a species falling within the genus.

The present invention only claims two compounds and salts thereof; by comparison, the narrowest claim of Borthwick claims thousands of compounds. There is not teaching or suggestion of any preferred compounds, nor the suggestion that the modification of certain compounds would lead to compounds with superior properties.

Furthermore, the present invention is a true selection invention over the prior art compounds described in Borthwick. The instant compounds are potent and selective oxytocin receptor antagonists. Liddle, et al., "The discovery of GSK221149A: A potent and selective oxytocin antagonist," *Bioorganic & Medicinal Chemistry Letters*, 18 (2008) 90-94. Liddle states that when compared to prior compounds disclosed in Borthwick, the instant compounds had greater oral exposure in rat in both DMSO/Peg and HPMC/Tween formulations, with good bioavailability and a half life of 1.4h, as well as low intrinsic clearance from three pre-clinical species (rat, dog, cynomolgus monkey) and low intrinsic clearance in human microsomes and is more potent than the prior art

compound. Liddle concluded that GSK221149A (the compound of claim 2) was selected as a clinical candidate because of its preferred overall profile. See Liddle, at 92.

In summary, the Examiner's obvious-type double patenting premises on a wrong legal theory that a species claim is *per se* obvious-type double patenting over a prior genus. In addition, the Examiner's *prima facie* obviousness analysis does not follow the framework set forth by the Federal Circuit in Baird, nor is it irrelevant to the obvious-type double patenting analysis. Applicant respectfully requests the obvious-type double patenting rejection be withdrawn.

Applicant submits that all reasons for rejection have been addressed and that the currently pending claims, in view of the above amendments and remarks, are allowable. Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned attorney at the number indicated below.

Respectfully submitted,



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